

### **Remarks**

Applicant appreciates the thorough examination of the present application as evidenced by the Final Office Action mailed May 21, 2003 and the subsequent Advisory Action mailed September 12, 2003.

Claims 1, 14-21, and 31-51 are pending in the present application. Claims 16-19, 21, and 45-49 were withdrawn from consideration and have now been canceled. Claims 1, 14, 15, 20, 31-44, and 50-51 stand rejected. The concerns raised by the Examiner are addressed below.

#### **I. Rejection Under 35 U.S.C. § 102**

Claims 1, 15, 31-36, 42-44 and 50-51 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,863,563 to Scheele (hereinafter, "Scheele") for the reasons set forth in the prior Office Action mailed November 13, 2002 (hereinafter, "November Action"). Moreover, the Advisory Action states that the Applicant's response to the November Action (Request for Reconsideration After Final Office Action Under 37 C.F.R. § 1.116 submitted August 21, 2003, hereinafter "Request for Reconsideration") "does NOT place the application in condition for allowance because . . . such methods are anticipated by the prior art." Advisory Action, page 2.

In order to expedite prosecution of the present application, Applicant has cancelled claim 1. Applicant has further amended claims 15, 31-36, 42-44 and 50-51 to depend from claim 14, or alternatively, to include specific recitations of claim 14 which is not subject to a rejection under 35 U.S.C. § 102(e). Accordingly, Applicant respectfully requests that this rejection be withdrawn.

#### **II. Claim Rejections Under 35 U.S.C. § 103**

Claims 1, 14, 15, 20, 31-44, and 50-51 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Scheele in view of U.S. Patent No. 5,162,348 to Glass (hereinafter, "Glass") for the reasons set forth in the November Action. More specifically, the November Action asserts that "it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was

made, to employ more than one of the known salts disclosed by Scheele in the therapeutical composition, or treating the patient with a bronchodilator before administering the instant composition.” November Action, page 3. Applicant respectfully traverses this rejection.

The test of obviousness is what the combined teachings of the references **would have suggested** to those of ordinary skill in the art. *See In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981) (emphasis added). Additionally, it is also well-established that the mere fact that references can be combined or modified does not render the resultant combination obvious **unless the prior art also suggests the desirability of the combination**. M.P.E.P. §2143.01, citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990) (emphasis added). As emphasized by the Court of Appeals for the Federal Circuit (hereinafter, "Federal Circuit"), to support combining references, evidence of a suggestion, teaching, or motivation to combine must be **clear and particular**, and this requirement for clear and particular evidence is not met by broad and conclusory statements about the teachings of references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999).

Turning specifically to the cited references, Scheele proposes administration of a pH-raising buffer to increase the rate of surfactant by type II alveolar cells. Consequently, Scheele does not describe the **methods** of the present invention. Moreover, Scheele erroneously sets forth proposals regarding the relationship between pH, type II alveolar cells, and surfactant secretion. As such, Applicant submits that one of ordinary skill in the art would not rely upon the proposals of Scheele directed toward using a pH-buffer effective to raise the pH of the aqueous fluid in the luminal microenvironment of the type II alveolar cells for the purpose of increasing surfactant secretion by type II alveolar (See Col. 2, lines 23-30) in order to arrive at a method comprising, among other things, administering at least one osmotically active compound wherein the at least one osmotically active compound comprises at least one salt to an airway surface of the subject in an amount effective to increase the volume of liquid on the airway surface, wherein the at least one osmotically active compound comprises at least one salt; and administering a

bronchodilator to said subject prior to or concurrently with said osmotically active compound in an amount sufficient to inhibit bronchoconstriction.

Applicant further notes that Scheele describes proposals that are **physiologically incapable** of producing the desired effect of treating chronic obstructive pulmonary disease as recited in claims of the present application. Thus, when considering Scheele in its **totality** for the disclosure that Scheele provides, it is noted that Scheele fails to provide any teaching or suggestion that would motivate one of ordinary skill in the art to arrive at the present invention.

Glass is employed to “teach that bronchodilators are well known to be useful for treating cystic fibrosis.” November Action, page 3. However, Glass does not supply **all** the missing recitations directed to a method of treating chronic obstructive pulmonary disease using, among other things, at least one osmotically active compound wherein the at least one osmotically active compound comprises at least one salt to an airway surface of the subject in an amount effective to increase the volume of liquid on the airway surface, wherein the at least one osmotically active compound comprises at least one salt; and administering a bronchodilator to said subject prior to or concurrently with said osmotically active compound in an amount sufficient to inhibit bronchoconstriction as disclosed in the claims of the present application. Thus, in this instance, there is no clear and particular evidence of a suggestion, teaching, or motivation to combine the cited references to arrive at the present invention.

Applicant reiterates that the test of obviousness is what the combined teachings of the references **would have suggested** to those of ordinary skill in the art. *See In re Keller*. In view of the erroneous teachings of Scheele, the combination of Scheele and Glass **would not have suggested** to one of ordinary skill in the art a method for treating chronic obstructive pulmonary disease in a subject in need of such treatment, comprising administering at least one osmotically active compound to an airway surface of the subject in an amount effective to increase the volume of liquid on the airway surface, wherein the at least one osmotically active compound comprises at least one salt; and administering a bronchodilator to said subject prior to

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or concurrently with said osmotically active compound in an amount sufficient to inhibit bronchoconstriction as recited in the claims of the present application.

Accordingly, Applicant respectfully submits that claims 1, 14, 15, 20, 31-44, 50-51 and new claim 52 are not unpatentable under 35 U.S.C. § 103(a) in view of Scheele in further view of U.S. Patent No. 5,162,348 to Glass, and respectfully requests that this rejection be withdrawn.

### **Conclusion**

In view of the foregoing amendments and remarks, Applicant respectfully requests that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,



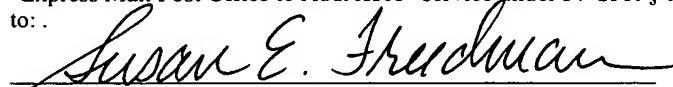
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Susan E. Freedman  
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